



US007183254B2

(12) **United States Patent**  
DePaoli et al.

(10) **Patent No.:** US 7,183,254 B2  
(45) **Date of Patent:** Feb. 27, 2007

(54) **USE OF LEPTIN FOR TREATING HUMAN LIPOATROPHY AND METHOD OF DETERMINING PREDISPOSITION TO SAID TREATMENT**

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(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 284 days.

(21) Appl. No.: 10/623,189

(22) Filed: Jul. 18, 2003

(65) **Prior Publication Data**

US 2005/0020496 A1 Jan. 27, 2005

**Related U.S. Application Data**

(63) Continuation of application No. 10/279,129, filed on Oct. 22, 2002, now abandoned.

(60) Provisional application No. 60/336,394, filed on Oct. 22, 2001.

(51) **Int. Cl.**

A61K 38/00 (2006.01)

A61K 38/16 (2006.01)

C07K 14/00 (2006.01)

(52) **U.S. Cl.** ..... 514/12; 424/184.1; 424/198.1;  
530/350

(58) **Field of Classification Search** ..... None  
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,521,283 A	5/1996	DiMarchi et al.
5,525,705 A	6/1996	DiMarchi et al.
5,532,336 A	7/1996	DiMarchi et al.
5,532,522 A	9/1996	DiMarchi et al.
5,532,523 A	9/1996	Basinski et al.
5,532,524 A	9/1996	Basinski et al.
5,554,727 A	9/1996	Basinski et al.
5,559,208 A	9/1996	Basinski et al.
5,563,243 A	10/1996	DiMarchi et al.
5,563,244 A	10/1996	DiMarchi et al.
5,563,245 A	10/1996	DiMarchi et al.
5,567,678 A	10/1996	DiMarchi et al.
5,567,803 A	10/1996	Basinski et al.
5,569,743 A	10/1996	DiMarchi et al.
5,569,744 A	10/1996	Basinski et al.
5,574,133 A	11/1996	DiMarchi et al.
5,580,954 A	12/1996	DiMarchi et al.
5,594,101 A	1/1997	Becker et al.
5,594,104 A	1/1997	Basinski et al.
5,605,886 A	2/1997	Basinski et al.
5,614,379 A	3/1997	MacKellar
5,691,309 A	11/1997	Basinski et al.

5,719,266 A	2/1998	DiMarchi et al.
5,756,461 A	* 5/1998	Stephens .....
5,922,678 A	* 7/1999	Stephens .....
6,258,932 B1	7/2001	Vahne
6,899,892 B2	* 5/2005	Gallagher et al. .... 424/439

FOREIGN PATENT DOCUMENTS

EP	725078	1/1996
EP	725079	1/1996
EP	741187	4/1996
EP	745610	4/1996
EP	736599	5/1996
EP	744408	5/1996
EP	835879	10/1997
WO	WO 96/05309	2/1996
WO	WO 96/22308	7/1996
WO	WO 96/27385	7/1996
WO	WO 96/23513	8/1996
WO	WO 96/23514	8/1996
WO	WO 96/23515	8/1996
WO	WO 96/23516	8/1996
WO	WO 96/23517	8/1996
WO	WO 96/23518	8/1996
WO	WO 96/23519	8/1996
WO	WO 96/31526	10/1996
WO	WO 96/34111	11/1996
WO	WO 96/34885	11/1996
WO	WO 96/35787	11/1996
WO	WO 96/37517	11/1996

(Continued)

OTHER PUBLICATIONS

Gavrilova et al., Leptin and diabetes in lipodystrophic mice, NATURE, Vo. 403, Feb. 24, 2000, pp. 850-851.\*

(Continued)

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(57) **ABSTRACT**

Leptin, leptin analogs, and leptin derivatives are used to treat patients with lipodystrophy. Leptin is effective against conditions of lipodystrophy for both genetic and acquired forms of the disease. A therapeutically effective amount of leptin can be administered in a variety of ways, including subcutaneously and using gene therapy methods. Methods of the present invention contemplate administration of leptin, leptin analogs, and leptin derivatives to patients having a leptin level of approximately 4 ng/ml or less before treatment.